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825 Challenger Drive, Green Bay, WI 54311-8328
 P: 920.469.1313 • F: 888.570.6460 (Enzymatic)
 P: 920.469.9099 • F: 920.469.4418 (Phyto)

0275 3 APR -7 P-230

MAR 30 2005

March 25, 2005

Office of Nutritional Products, Labeling &
 Dietary Supplements, HFS 810
 Center for Food Safety and Applied Nutrition
 Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	Protective Breast Formula is a combination of clinically and scientifically studied ingredients that support the immune system and cellular health.* It includes turmeric extract, Indoplex® with DIM, calcium d-glucarate, maitake d-fraction, green tea extract, grape seed extract and vitamin D3, bringing together some of the most widely-studied ingredients that support immune health.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indoplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifola frondosa) Mushroom Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

975 0162

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15948

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer



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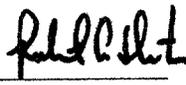
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	Specifically formulated to provide optimum benefits for women*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indolplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifola frondosa) Mushroom Extract

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	Includes the potent natural immune boosters and antioxidants: Indoplex®, green tea extract, maitake D-fraction, turmeric, vitamin D3 cholecalciferol and grape seed extract*	Vitamin D (as cholecalciferol), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indoplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifola frondosa) Mushroom Extract

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	The ingredients in Protective Breast Formula were selected because each provides demonstrated breast health support through one or more different pathways, including antioxidants, hormone detoxification, and immune system support.* When used in conjunction with a balanced diet and healthy lifestyle choices, Protective Breast Formula provides superior support for breast tissue health.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indolplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifolia frondosa) Mushroom Extract

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Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

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Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	Supplemental antioxidants from food or supplements can boost the body's own natural antioxidant defenses.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indolplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifolia frondosa) Mushroom Extract

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Sincerely,



Michael P. Devereux
Chief Financial Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	Grape seed extract is a powerful antioxidant ingredient found in Protective Breast Formula.* In a scientific study, grape seed extract even exhibited more powerful antioxidant activity than vitamins C and E.*	Grape (Vitis vinifera) Seed Extract,

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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	Other research has shown that the antioxidant activity of grape seed extract aids in the overall functioning of healthy cellular production and immune support.* A recent study in an animal model found that grape seed extract was associated with a 50% increased benefit in breast cell health.*	Grape (Vitis vinifera) Seed Extract,

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By: 

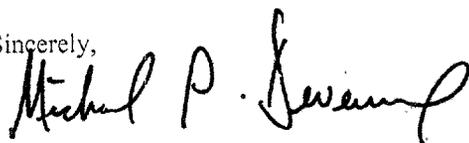
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	Green tea is well known for its antioxidant abilities as well.* Green tea compounds, called polyphenols or catechins are the components studied for their beneficial effects.* To date, most research has centered around a catechin of green tea called epigallocatechin-3-gallate, or simply, EGCG. In scientific and clinical studies, EGCG from green tea works as an overall antioxidant and a powerful scavenger of free radicals.* Specifically, studies have found EGCG supports healthy breast cell development.*	Green Tea (Camellia sinensis) Leaf Extract

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Title: Senior Vice President of Scientific Affairs

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Protective Breast Formula™*	Green tea has been shown in research studies to both increase the activity of antioxidant production systems (glutathione peroxidase and superoxide dismutase enzyme), as well as protect lipids and proteins from oxidation.* Finally green tea has also shown COX-2 inhibition, and support for healthy cell replication and development.*	Green Tea (Camellia sinensis) Leaf Extract

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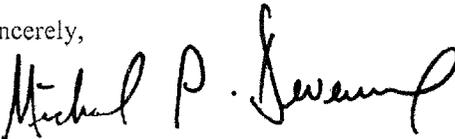
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	Recent research also shows a link between COX-2 inhibition and support of healthy breast tissue formation.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indolplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifolia frondosa) Mushroom Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	In scientific studies, turmeric shows COX-2 inhibition and general support for healthy cell development.* Turmeric seems to be COX-2 preferential—not inhibiting the activity of the beneficial COX-1 enzyme involved in supporting the stomach lining.* Additional recent research has investigated turmeric's ability to scavenge free radicals.*	Turmeric (Curcuma longa) Rhizome Extract

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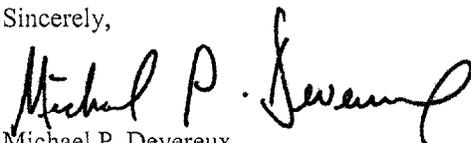
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Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	For years, an observational association has been noted between healthy estrogen balance and a high dietary intake of vegetables, such as broccoli, cauliflower, and cabbage.* Scientific study determined that such cruciferous vegetables contain several phytochemicals, including diindolylmethane (DIM).*	Indolplex Complex

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/27/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer



ENZYMATIC THERAPY
INCORPORATED

What **Better** feels like.™

March 28, 2005

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	Research has shown that consumption of DIM increases the ratio of desirable 2-hydroxy and 2-methoxy estrogen metabolites over the undesirable 16-hydroxyestron estrogen metabolites.* Scientific studies have also found that DIM directly supports healthy cell development in breast tissue.*	Indoplex Complex

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/28/05

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Sincerely,

Michael P. Devereux
Chief Financial Officer

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas ◊ PhytoPharmica
Tyler Encapsulations ◊ Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 ◊ F: 503.582.0467

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&
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 ◊ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ◊ F: 920.469.4418 (Phyto)



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	Extracts of maitake have also been investigated for their effects on immune system health and cellular development.*	Maitake (Frifolia frondosa) Mushroom Extract

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By: 

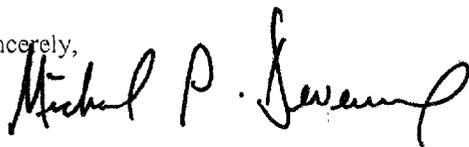
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/28/05

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	D-fraction is one of the key compounds in maitake mushrooms.* Its primary benefit is to boost the activity of important immune system cells.* In a clinical study, maitake D-fraction enhanced natural killer cell activity by 1.2 to 2.7 times.* Other clinical and scientific studies have been encouraging as well, showing that maitake D-fraction induced a healthy immune system and cellular response.* All the participants in a clinical study experienced increased natural killer activity and support of healthy cellular development.*	Maitake (Frifola frondosa) Mushroom Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster
Robert Doster
Title: Senior Vice President of Scientific Affairs

Date: 3/28/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Protective Breast Formula™*	<p>The benefits of vitamin D for bone health have been well documented.* New epidemiologic studies have now shown that higher dietary intake of vitamin D is associated with support for breast health.* Cholecalciferol, the biologically active form of vitamin D (also known as vitamin D3) is now the focus of research to determine exactly how vitamin D's benefits for breast tissue are attained.*</p> <p>Scientific studies have shown that cholecalciferol encourages healthy cell growth and cell differentiation.* These studies show that cholecalciferol enhances the body's own natural immune defense, support normal cellular health and support TNF-alpha (a protein involved with inflammation)-induced defense of breast cell tissues.*</p>	Vitamin D (as cholecalciferol)

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